IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

STATE OF West Virginia)
) SS. **AFFIDAVIT OF CASSANDRA BIRD**
COUNTY OF Monongalia)

CASSANDRA BIRD, being first duly sworn, according to law, and having personal knowledge of the matters contained herein, deposes and states as follows:

1. I am currently the Senior Director of Quality Assurance for Mylan Pharmaceuticals, Inc. ("Mylan").

2. Mylan, Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business in West Virginia. Finally, Mylan Bertek Pharmaceuticals, Inc. is a seller/distributor that is incorporated in Texas, but has no offices or physical facilities.

3. On April 24, 2008, Mylan was informed of a voluntary Class I recall of all marketed lots of Digitek® tablets within expiry by the manufacturer, Actavis Totowa LLC. Mylan distributed Digitek® for Actavis under the Bertek and UDL labels.

4. At the time of the recall, I was the Director of Quality Assurance and Recall Coordinator for Mylan.

5. On or about April 24, 2008, Mylan retained the services of Stericycle, Inc. for distribution of the Digitek® recall notification packet and consumer product return kit and tracking of the recalled product.

6. The recall notification packet was initially sent out to over 77,000 wholesalers, pharmacies, hospitals, clinics, and long-term care facilities, as well as to approximately 170 Mylan direct accounts.

7. The recall notification packet identified the product, the reason for the recall, and action items. Recipients of the recall notification packet were instructed to "identify your retail-level customers and notify them at once of this product recall"; and retail-level customers who had further distributed the recalled product were to "instruct the consumer to contact Stericycle at 1-888-276-6166 for the return of the product." *See* Exh. A, recall notification packet. Further instructions included carrying out a physical count of recalled product, recording the data on a business reply card, and returning recalled product to Stericycle facilities in Indiana. *Id.*

8. In conjunction with the mailing of the recall notification packets, the Food & Drug Administration requested that Mylan perform a Level A (100%) effectiveness check on wholesalers, pharmacies, hospitals, clinics, and Mylan direct accounts. For the effectiveness checks, outbound calls were placed to 45,231 non-responders to see if they received the recall notification packet, had any affected product (if so, a return kit is sent), or if the non-responders had any other questions or comments.

9. Mylan submitted recall status reports to the FDA every week until June 17, 2008. After June 17, 2008, and until July 30, 2008, Mylan submitted status reports to the FDA approximately every two weeks. After July 30, 2008, Mylan submitted status reports to the FDA approximately every month.

10. In or about December 2008, Stericycle completed the effectiveness check, which resulted in 40,588 customers responding to the questionnaire. From the effectiveness check Stericycle learned that 870 facilities had closed; 1969 customers could not be contacted; and 1,804 customers were uncooperative.

11. As of February 10, 2010, Stericycle has received 33,332 business reply card responses and/or product returns from pharmacies, hospitals, clinics, and Mylan direct accounts, which included 36,346,376 units/tablets.

12. Stericyle received 168,193 inquiries from consumer consignees. Only 164,457 consumer consignees requested a consumer product return kit.

13. Upon contacting Stericycle, consumers received a "Digitek® Consumer Return Kit" outlining the requisite steps to receive a refund on recalled product. *See* Exh. B, Consumer Return Kit. Consumers returning unused Digitek®, together with a valid pharmacy receipt received a refund for the last prescription filled; consumers who provided a valid pharmacy receipt, but destroyed or disposed of remaining Digitek®, also received a refund. Consumers without a valid pharmacy receipt could also receive a refund on a per-tablet basis.

14. Although the Consumer Return Kit indicates that the required documents (consumer authorization form and receipt) and return of product must be completed and postmarked no later than October 31, 2008 to be eligible for a refund, Stericycle has continued to process and reimburse returns to date.

15. As of February 10, 2010, Stericycle had received 63,784 business reply card responses and/or product returns, which included 6,026,847 units/tablets from consumer consignees.

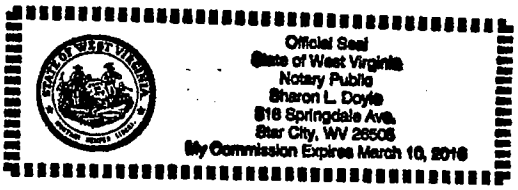
FURTHER AFFIANT SAITH NAUGHT.

Cassandra Bird
CASSANDRA BIRD

SWORN TO AND SUBSCRIBED IN MY PRESENCE this 17th day of February, 2010.

Sharon L. Doyle
NOTARY PUBLIC

073021.000031.1114018.1



URGENT: DRUG RECALL

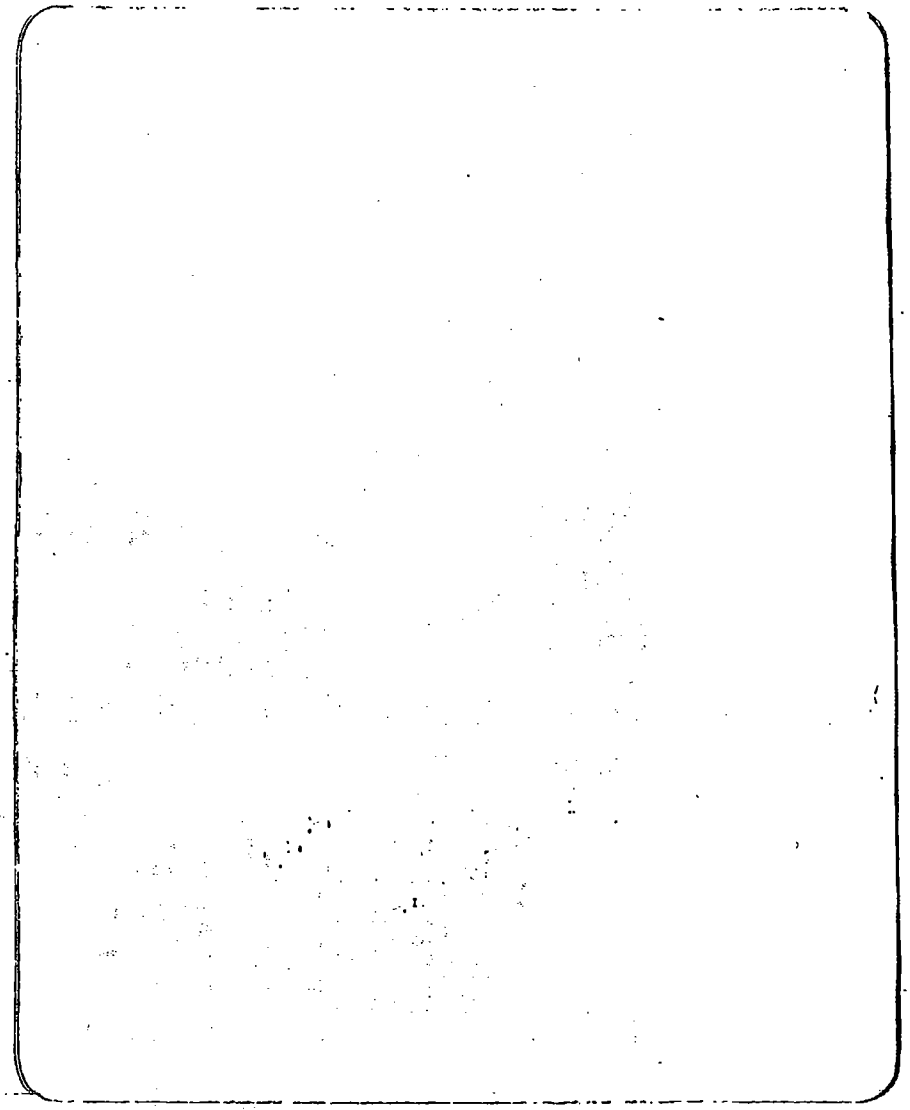


EXHIBIT A

Any Business Name
Any Street
Any City, XX 12345

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO 2702 INDIANAPOLIS IN

POSTAGE WILL BE PAID BY ADDRESSEE

STERICYCLE INC
6026 LAKESIDE BLVD
INDIANAPOLIS IN 46209-7912

STERICYCLE
(800) 668-4391
2670 EXECUTIVE DR SUITE A
INDIANAPOLIS IN 46241

LTR 1 OF 1

ATTN: PHARMACY MGR / RECALL COORD

SHIP TO: N/A
ANY BUSINESS NAME
ANY STREET

ANY CITY XX 12345

NY 122 9-02

UPS NEXT DAY AIR SAVER

TRACKING: 1Z E38 095 13 2533 3984

1P

BILLING: P/P

N22879454D1862-164

URC75.5A 02/2008

Digitek® (digoxin tablets, USP)

NDC #	STRENGTH	SIZE	SEALED BOTTLES ON HAND	PARTIAL BOTTLES ON HAND	TABLET COUNT PER PARTIAL BOTTLE(S)
62794-145-01	125 mcg (0.125 mg)	Bottles of 100s			
62794-145-10	125 mcg (0.125 mg)	Bottles of 1000s			
62794-145-56	125 mcg (0.125 mg)	Bottles of 5000s			
62794-146-01	250 mcg (0.25 mg)	Bottles of 100s			
62794-146-10	250 mcg (0.25 mg)	Bottles of 1000s			
62794-146-56	250 mcg (0.25 mg)	Bottles of 5000s			

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, even if you do not have the recalled product. Thank you.

Signature _____ Title _____

Name _____ Phone _____

BUSINESS REPLY CARD

Mylan Pharmaceuticals, Inc.

April 28, 2008

Event 1862

ID 22879454

Any Business Name

Digitek® (digoxin tablets, USP)

NDC #	STRENGTH	SIZE	SEALED BOTTLES ENCLOSED	PARTIAL BOTTLES ENCLOSED	TABLET COUNT PER PARTIAL BOTTLE(S)
62794-145-01	125 mcg (0.125 mg)	Bottles of 100s			
62794-145-10	125 mcg (0.125 mg)	Bottles of 1000s			
62794-145-56	125 mcg (0.125 mg)	Bottles of 5000s			
62794-146-01	250 mcg (0.25 mg)	Bottles of 100s			
62794-146-10	250 mcg (0.25 mg)	Bottles of 1000s			
62794-146-56	250 mcg (0.25 mg)	Bottles of 5000s			

The following information is required to assure proper crediting:

Wholesaler Debit Memo: _____

PACKING SLIP

Mylan Pharmaceuticals, Inc.

April 28, 2008

Event 1862

ID 22879454

Any Business Name

Ship To: STERICYCLE RECALL COORDINATOR
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
22879454
1862

IN 462 9-01

UPS GROUND
TRACKING: 1Z E38 010 06 9192 8176

023 (10/06)

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All followup will be based on this shipping information.

TRACKING: 1Z E38 010 06 9192 8176

ID 22879454 Event 1862

Any Business Name

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

Recall initiated by the manufacturer: Actavis Totowa LLC (formerly known as Amide Pharmaceuticals, Inc.)
Product Distributed by: Mylan Pharmaceuticals, Inc. under a "Bertek" Label

PRODUCT	NDC	Name	Strength	Size	Lot #
	62794-145-01	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 100s	All lots
	62794-145-10	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 1000s	All lots
	62794-145-56	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 5000s	All lots
	62794-146-01	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 100s	All lots
	62794-146-10	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 1000s	All lots
	62794-146-56	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 5000s	All lots

REASON

Mylan Pharmaceuticals Inc. is continuing a voluntary recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP). This product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate. Product was distributed nationwide between March 2006 and April 2008.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received by Actavis.

ACTION

1. Immediately examine your inventory and quarantine and discontinue distribution of all lots within expiry.
2. In addition, if you may have further distributed the recalled product, please identify your retail-level customers and notify them at once of this product recall.
3. Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall. They should instruct the consumer to contact Stericycle at 1-888-276-6166 for the return of the product.
4. Consumers should discuss their treatment options and change in therapy with their physician.
5. Carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter. Federal Regulations require a physical count.
6. Mail the postage paid Business Reply Card to the address provided. Federal regulations require that you return this completed card even if you do not have the recalled product.
7. Return the recalled product with the Packing Slip using the prepaid UPS RS shipping label to:
   Stericycle
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

OTHER

This recall extends to the consumer level.

Credit/check will be issued for return of recalled product.

Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.

For questions regarding Digitek® Tablets (digoxin tablets, USP) recall, please call Stericycle at 1-888-276-6166.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

1862_0201AS

DIGITEK® CONSUMER RETURN KIT

Thank you for your recent inquiry regarding the Digitek® (digoxin tablets, USP) product recall. Stericycle is handling all refund requests associated with the Digitek® product recall. Thus, consumers should not ask their pharmacy for a refund and should follow Stericycle's enclosed instructions to process refund requests. Please read the following information carefully and adhere to the requirements pertaining to your situation.

A. For consumers who are able to return the remaining portion of their Digitek® prescription:

1. Place the unused Digitek®, in its original pharmacy container (if possible), in the enclosed shipping package.
2. Place your valid pharmacy receipt in the enclosed shipping package. A valid pharmacy receipt includes the name, address, and phone number of the dispensing pharmacy, your name, the prescription number, product name, product strength, quantity of product, the date your prescription was filled, and the amount that you paid out-of-pocket for the prescription. Your prescription must have been filled between March 2006 and April 2008 to be eligible for a refund.
3. Complete and sign the *Consumer Authorization Form* at the bottom of this page and include it in the shipping package.
4. Seal the shipping package and affix the prepaid USPS label to the outside and drop in any mailbox.

B. For consumers who destroyed or disposed of the remaining portion of their Digitek® prescription:

NOTE: If you have destroyed or disposed of your Digitek® and cannot return it, you may still be eligible for a refund if you have a valid pharmacy receipt (limited to one receipt) as described in #1 below.

1. Place your valid pharmacy receipt in the enclosed shipping package. A valid pharmacy receipt includes the name, address, and phone number of the dispensing pharmacy, your name, the prescription number, product name, product strength, quantity of product, the date your prescription was filled, and the amount that you paid out-of-pocket for the prescription. Your prescription must have been filled between March 2006 and April 2008 to be eligible for a refund.
2. You must complete and sign the enclosed *Consumer's Certification of Inability to Return Digitek®* and include it in the shipping package.
3. You must also complete and sign the *Consumer Authorization Form* at the bottom of this page and include it in the shipping package.
   Note: **Both the *Consumer's Certification of Inability to Return Digitek®* and the *Consumer Authorization Form* must be signed and returned in order to qualify for a refund if you are not returning the Digitek®.**
4. Seal the shipping package and affix the prepaid USPS label to the outside and drop in any mailbox.

Eligibility for a refund requires a valid pharmacy receipt (limited to one receipt) as described above indicating that your prescription was dispensed between March 2006 and April 2008. If you are not returning product and you do not have a valid pharmacy receipt, you are not eligible for a refund.

This Consumer Return Kit and required documents must be completed and postmarked no later than **October 31, 2008**, in order to be eligible for a refund. Refund requests may take up to 12 weeks from the time that Stericycle receives the completed Consumer Return Kit.

For shipping assistance and/or questions about the return process, contact Stericycle at **1-888-276-6166.**

CONSUMER AUTHORIZATION FORM:* *(Signature required)

I understand that the information I have provided in connection with my request for a refund on Digitek® will be used by Stericycle for any purpose related to my request for a refund. As necessary, Stericycle may contact my pharmacy to process my request for a refund and to verify the information I have provided.

By signing below, I authorize Stericycle to use the information I have provided as set forth above. For such purpose, I understand that Stericycle may provide to my pharmacy a copy of this completed Authorization and all other information I have given to Stericycle to process my request for a refund.

Signature: _____ **Print Name:** _____ **Date:** _____

Address: _____ **Telephone:** _____

_____

_____

1863_0101AS

EXHIBIT B

Consumer's Certification of Inability to Return Digitek® (digoxin tablets, USP)
(For consumers who have destroyed or disposed of their Digitek® and cannot return it)

The undersigned certifies as follows:

1. I purchased Digitek® as shown on the valid pharmacy receipt submitted to Stericycle.

2. I still had some unused Digitek® in my possession on April 30, 2008.

3. However, I cannot return my unused Digitek® because I destroyed or disposed of it as described below.

4. I request a refund for this product based on the statements and authorization in this document.

(Please fill in the blanks or check the appropriate boxes below)

Name and address of pharmacy where Digitek® was purchased: _____
_____

Telephone number of pharmacy (if available): ( )____ - _____

Amount of Digitek® (number of tablets) I still had in my possession on April 30, 2008:

.25 mg _____ .125 mg _____

I am unable to return this product because:

- ☐ I destroyed or disposed of it
- ☐ I returned it to my physician
- ☐ I returned it to my pharmacy but did not get a refund
- ☐ Other (please explain): _____

I understand that I cannot receive a refund if I keep any portion of unused Digitek® or if I have already received a refund from any other source for this prescription.

Signature: _____ Date: _____

Print name: _____

Address: _____ Telephone: _____

_____

1865_Q102AS

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

All lots within expiry

Below is a listing of affected Digitek® product by NDC number

NDC	Name	Strength
62794-145-01	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)
62794-145-10	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)
62794-145-56	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)
62794-146-01	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)
62794-146-10	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)
62794-146-56	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)

Event 1863
ID 22879460
Any Business Name

If you have affected product or a valid pharmacy receipt please carefully read and follow the instructions on the attached form and place all necessary forms, completed and signed, in the shipping package with your return.

After ensuring all necessary forms are complete and your shipping package is ready to be mailed, remove the prepaid USPS label from the bottom of this page and affix it to the shipping package then drop in any mailbox.

Please note, if you are not returning product and you do not have a valid pharmacy receipt, you are not eligible for a refund.

Event 1863
ID 22879460
Any Business Name

ID# 22879460 Event 1863
Any Business Name
Any Street
Any City XX 12345

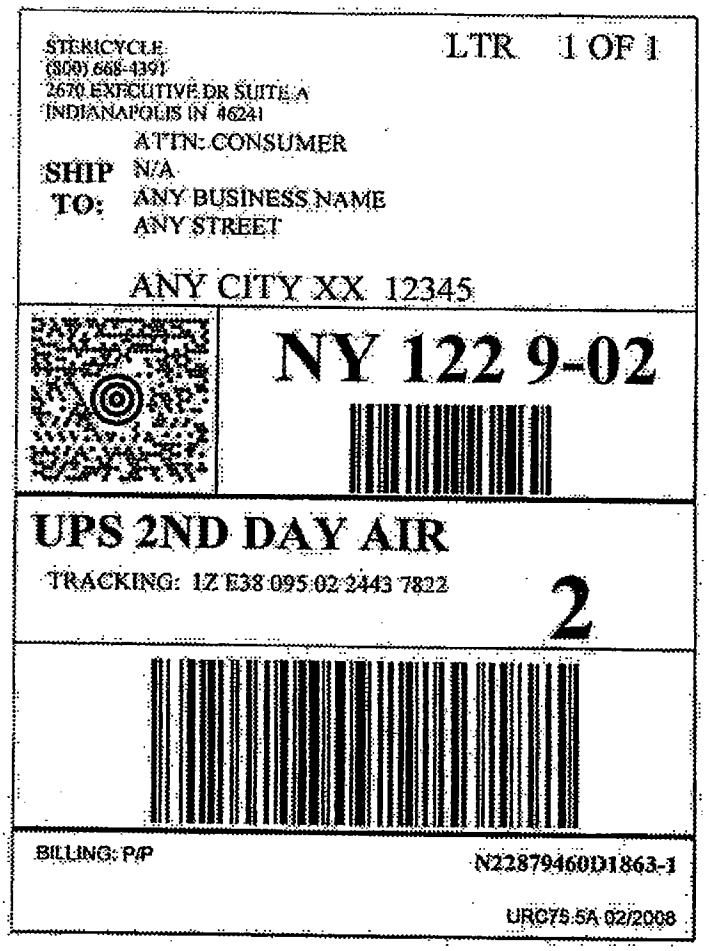
NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

PRIORITY MAIL

MERCHANDISE RETURN LABEL
PERMIT NO. 20069
STERICYCLE
INDIANAPOLIS IN 46241
2670 EXECUTIVE DRIVE

POSTAGE DUE UNIT
US POSTAL SERVICE
PO BOX 9998
INDIANAPOLIS IN 46241-9998

ID# 22879460 Event 1863
Any Business Name



STERICYCLE
(800) 668-4391
2670 EXECUTIVE DR SUITE A
INDIANAPOLIS IN 46241

LTR 1 OF 1

ATTN: CONSUMER
SHIP TO: N/A
ANY BUSINESS NAME
ANY STREET

ANY CITY XX 12345

NY 122 9-02

UPS 2ND DAY AIR

TRACKING: 1Z E38 095 02 2443 7822

2

BILLING: P/P

N22879460D1863-1

URC75.5A 02/2008

IMPORTANT INFORMATION ENCLOSED